

EXHIBIT 5

September 2011

DRUG PRICING

Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement

U.S. Government Accountability Office

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ACCOUNTABILITY ★ INTEGRITY ★ RELIABILITY

Why GAO Did This Study

The Health Resources and Services Administration (HRSA), within the Department of Health and Human Services (HHS), oversees the 340B Drug Pricing Program, through which participating drug manufacturers give certain entities within the health care safety net—known as covered entities—access to discounted prices on outpatient drugs. Covered entities include specified federal grantees and hospitals. The number of covered entity sites has nearly doubled in the past 10 years to over 16,500.

The Patient Protection and Affordable Care Act (PPACA) mandated that GAO address questions related to the 340B program. GAO examined: (1) the extent to which covered entities generate 340B revenue, factors that affect revenue generation, and how they use the program; (2) how manufacturers' distribution of drugs at 340B prices affects covered entities' or non-340B providers' access to drugs; and (3) HRSA's oversight of the 340B program. GAO reviewed key laws and guidance, analyzed relevant data, and conducted interviews with 61 340B program stakeholders selected to represent a range of perspectives, including HRSA, 29 covered entities, 10 manufacturers and representatives, and 21 others. Selection of stakeholders was judgmental and thus, responses are not generalizable.

What GAO Recommends

To ensure appropriate use of the 340B program, GAO recommends that HRSA take steps to strengthen oversight regarding program participation and compliance with program requirements. HHS agreed with our recommendations.

View [GAO-11-836](#). For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

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What GAO Found

Thirteen of the 29 covered entities we interviewed reported that they generated 340B program revenue that exceeded drug-related costs, which includes the costs of purchasing and dispensing drugs. Of those remaining, 10 did not generate enough revenue to exceed drug-related costs, and 6 did not report enough information for us to determine the extent to which revenue was generated. Several factors affected 340B revenue generation, including drug reimbursement rates. Regardless of the amount of revenue generated, all covered entities reported using the program in ways consistent with its purpose. For example, all covered entities reported that program participation allowed them to maintain services and lower medication costs for patients. Entities generating 340B program revenue that exceeded drug-related costs were also able to serve more patients and to provide additional services.

According to the 61 340B program stakeholders we interviewed, manufacturers' distribution of drugs at 340B prices generally did not affect providers' access to drugs. Specifically, 36 stakeholders, including those representing manufacturers, covered entities, and non-340B providers, did not report any effect on covered entities' or non-340B providers' access. The remaining 25, also representing a wide range of perspectives on the 340B program, reported that it affected access primarily in two situations: (1) for intravenous immune globulin (IVIG), a lifesaving drug in inherently limited supply; and (2) when there was a significant drop in the 340B price for a drug resulting in increased 340B demand. In both situations, manufacturers may restrict distribution of drugs at 340B prices because of actual or anticipated shortages. Stakeholders reported that restricted distribution of IVIG resulted in 340B hospitals having to purchase some IVIG at higher, non-340B prices. They also reported that restricted distribution when the 340B price of a drug dropped significantly helped maintain equitable access for all providers.

HRSA's oversight of the 340B program is inadequate to provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements—such as, entities' transfer of drugs purchased at 340B prices only to eligible patients, and manufacturers' sale of drugs to covered entities at or below the 340B price. HRSA primarily relies on participant self-policing to ensure program compliance. However, its guidance on program requirements often lacks the necessary level of specificity to provide clear direction, making participants' ability to self-police difficult and raising concerns that the guidance may be interpreted in ways inconsistent with the agency's intent. Other than relying on self-policing, HRSA engages in few activities to oversee the 340B program. For example, the agency does not periodically confirm eligibility for all covered entity types, and has never conducted an audit to determine whether program violations have occurred. Moreover, the 340B program has increasingly been used in settings, such as hospitals, where the risk of improper purchase of 340B drugs is greater, in part because they serve both 340B and non-340B eligible patients. This further heightens concerns about HRSA's current approach to oversight. With the number of hospitals in the 340B program increasing significantly in recent years—from 591 in 2005 to 1,673 in 2011—and nearly a third of all hospitals in the U.S. currently participating, some stakeholders, such as drug manufacturers, have questioned whether all of these hospitals are in need of a discount drug program.

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Abbreviations

ADAP	AIDS Drug Assistance Program
CMS	Centers for Medicare & Medicaid Services
DSH	disproportionate share hospital
FQHC	federally qualified health center
GPO	group purchasing organization
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IVIG	intravenous immune globulin
PHSA	Public Health Service Act
PPACA	Patient Protection and Affordable Care Act
PSSC	Pharmacy Services Support Center
PVP	Prime Vendor Program

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G A O

Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

September 23, 2011

The Honorable Tom Harkin
Chairman
The Honorable Michael B. Enzi
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
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House of Representatives

Our nation's health care safety net provides services to low-income, uninsured, underinsured, and other individuals who experience barriers accessing care, regardless of their ability to pay. Certain types of providers within the safety net have access to discounted prices on outpatient drugs through the 340B Drug Pricing Program.¹ The program, created in 1992 and named for the statutory provision authorizing it in the Public Health Service Act (PHSA),² requires drug manufacturers to give 340B discounts to entities covered under the law—known as covered entities—in order to have their drugs covered by Medicaid.³

Covered entities include clinics and hospitals that provide general health care services, as well as those that serve patients with specific conditions or diseases, and are typically eligible for the program because they receive some type of federal support, such as a federal grant. According

¹Outpatient drugs covered under the 340B program may include: prescription drugs approved by the Food and Drug Administration; certain over-the-counter drugs provided as prescriptions; biological products, other than vaccines, that can be dispensed only by a prescription; and insulin approved by the Food and Drug Administration. 42 U.S.C. §§ 256b(b)(2), 1396r-8(k)(2). When payment for an outpatient drug is bundled with payment for other services, the drug is not covered by the 340B program.

²42 U.S.C. § 256b.

³Medicaid is a joint federal-state program that finances health care for certain categories of low-income individuals. Medicaid programs vary from state to state.

to the Health Resources and Services Administration (HRSA), the agency within the Department of Health and Human Services (HHS) responsible for administering and overseeing the 340B program, the purpose of the program is to enable covered entities to stretch scarce federal resources to reach more eligible patients, and provide more comprehensive services.⁴ Covered entities' current spending on 340B drug purchases is estimated to be about \$6 billion annually.

Participation in the 340B program is voluntary for both covered entities and drug manufacturers, but there are strong incentives to participate. Covered entities can realize substantial savings through 340B price discounts—an estimated 20 to 50 percent off the cost of drugs, according to HRSA. In addition, covered entities can generate 340B revenue.⁵ For example, covered entities can purchase drugs at the 340B price for all patients eligible under the program regardless of their income or insurance status, and generate revenue, such as through a patients' insurance reimbursement, that may exceed the 340B price paid for the drugs.⁶ As of July 2011, there were more than 16,500 covered entity sites

⁴HRSA bases this view on language in a House Energy and Commerce Committee Report pertaining to language similar to what eventually became section 340B of the PHSA. See H. Rep. No. 102-384, Pt. 2, at 12 (1992) (discussing bill to amend the Social Security Act); See also Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the PHSA).

⁵For this report, we define 340B revenue as all monies received by covered entities for drugs they purchase at the 340B price, whether or not the revenue meets or exceeds the costs paid for the drugs.

⁶In 1996, HRSA issued a definition of a 340B patient that defines the situations under which covered entities can use drugs purchased at 340B prices for their patients. While income and insurance status do not dictate whether a patient is eligible under the program, certain patients, such as those who do not receive health care services consistent with the scope of a grant that made an entity eligible for the program or those whose only service from the covered entity is the dispensing of drugs, are prohibited from receiving drugs purchased at the 340B price. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

enrolled in the program—about double the number reported in 2001.⁷ Because they must participate in the 340B program to receive Medicaid reimbursement for their drugs, incentives for participation by drug manufacturers also are strong. According to HRSA, most manufacturers that produce outpatient drugs have participated in the program since its inception.

HRSA requires program participants to meet certain conditions set forth both in law and agency guidance. For example, under the PHSA, covered entities are prohibited from transferring 340B drugs to individuals who are not eligible patients of the entities.⁸ Similarly, to help ensure covered entities receive the discounts they are entitled to, HRSA has issued nondiscrimination guidance prohibiting drug manufacturers from distributing drugs in ways that would discriminate against covered entities compared to other, non-340B healthcare providers.⁹ This includes not conditioning the sale of drugs to covered entities on restrictive conditions, such as requiring them to commit to minimum purchase amounts, which would discourage entities from participating in the program. However, stakeholders, including both covered entities and drug manufacturers, have raised questions about the extent to which 340B program requirements are followed and the extent to which HRSA ensures compliance. Further, because the 340B program has no requirements on how 340B revenue can be used,¹⁰ stakeholders, such as drug manufacturers, have raised questions about covered entities' generation of revenue and whether they are using it in ways consistent with the purpose of the program. Additionally, due to continued growth in the

⁷Data are the most recent available from HRSA's covered entity database and represent both unique covered entities and all their eligible sites, such as satellite clinics. According to HRSA, there are about 3,200 unique organizations currently participating in the program—the agency was unable to provide historical data on unique organizations for all entity types. Additionally, because a covered entity may enroll under any and all eligible grant types it receives, it is possible that certain unique organizations and eligible sites are reflected in the database more than once. However, HRSA estimates that this overlap represents less than 5 percent of all listings in the database.

⁸42 U.S.C. § 256b(a)(5)(B).

⁹Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 58 Fed. Reg. 68922 (Dec. 29, 1993).

¹⁰According to HRSA, while there are no 340B-specific requirements, all covered entities eligible for the program based on their grantee status may be required to use 340B revenue in accordance with their grant requirements.

number of covered entities participating in the program, some stakeholders have raised questions about whether increased use of 340B discounts shifts a larger share of drug costs to others in the health care system.

The Patient Protection and Affordable Care Act (PPACA) amended the 340B program by expanding entity eligibility for the program to include additional types of hospitals.¹¹ PPACA also contained provisions to improve 340B program integrity, and included a provision explicitly prohibiting manufacturers from discriminating against covered entities in the sale of 340B drugs, consistent with HRSA's nondiscrimination guidance.¹² The passage of PPACA has raised some questions for 340B stakeholders about the program. For example, although proponents of the explicit prohibition on manufacturers contend that it is necessary to prevent discrimination against covered entities, critics are concerned about how it could affect non-340B providers' access to drugs.¹³ Additionally, PPACA extends health insurance coverage to more Americans, and some stakeholders, such as drug manufacturers, have questioned whether covered entities will need the discounts provided through the 340B program given this increased coverage.

PPACA directed us to address several questions related to the 340B program. In response to the mandate, we examined: (1) the extent to which covered entities generate 340B revenue, factors that affect their revenue generation, and how entities use the program; (2) how manufacturers' distribution of drugs at 340B prices affects providers' access to drugs, whether those providers are covered entities or non-340B providers; and (3) HRSA's oversight of the 340B program.

¹¹Entities that became eligible for the 340B program through PPACA include certain critical access hospitals, sole community hospitals, rural referral centers, and freestanding cancer hospitals. See Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 (2010) as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302, 124 Stat. 1029, 1082.

¹²Pub. L. No. 111-148, § 7102(b).

¹³For this report, we consider providers as having access to a drug if they are able to obtain the amount necessary to meet the needs of their patients—for covered entities this includes being able to obtain the drug at the 340B price.

To examine the extent to which covered entities generate revenue through their participation in the 340B program, factors that affect their revenue generation, and how entities use the program, we conducted interviews with a judgmental sample of 29 covered entity organizations primarily selected to represent five covered entity types located in five states. We selected entity types based on factors, including high levels of participation in the 340B program and variation in organizational structure and the types of services provided. We selected states based on factors, including geographic variation and the percentage of uninsured in the state. Specifically, we interviewed 7 federally qualified health centers (FQHC),¹⁴ 5 family planning clinics, 5 AIDS Drug Assistance Programs (ADAP), 5 hemophilia treatment centers, and 5 general acute care hospitals with a Medicare disproportionate share hospital (DSH) adjustment percentage of greater than 11.75 percent¹⁵—in this report we refer to these hospitals as DSH hospitals.¹⁶ These entities were located in Illinois, Massachusetts, Tennessee, Texas, and Utah. We specifically selected Massachusetts to gain a better understanding of the potential effect of PPACA’s health insurance reforms on the 340B program.¹⁷ In addition to interviewing covered entities located in the five states, we conducted interviews with 2 additional DSH hospitals located in other states, because of questions raised in stakeholder interviews about how these hospitals were using the program. When possible, we collected

¹⁴FQHCs are urban or rural health centers that provide comprehensive community-based primary and preventive care services to medically underserved populations and have received a “Federally Qualified Health Center” designation from the Centers for Medicare & Medicaid Services (CMS).

¹⁵General acute care hospitals are eligible for the 340B program when they have a Medicare DSH adjustment percentage of greater than 11.75 percent and meet certain other requirements. Medicare is the federally financed health insurance program for persons aged 65 or over, certain individuals with disabilities, and individuals with end-stage renal disease. The Medicare DSH adjustment percentage is an additional Medicare payment to acute care hospitals paid under the inpatient prospective payment system—a Medicare reimbursement method based on a predetermined, fixed amount. A hospital’s DSH adjustment percentage is generally based on its DSH patient percentage, which is a statutory formula created to identify hospitals that treat a significantly disproportionate number of low-income Medicare and Medicaid patients.

¹⁶While additional types of hospitals are eligible for the 340B program, we only interviewed DSH hospitals because the remaining hospital types had only recently started participating in the program.

¹⁷In 2006, Massachusetts implemented comprehensive state-level health insurance reform that was similar to PPACA’s national-level reform.

relevant documentation from covered entities. Although we selected covered entities to interview that represented a variety of entity types, not all covered entity types are represented. Further, our selection of covered entities was judgmental, and our sample is not generalizable. (See appendix I for more details on how we selected covered entities and appendix II for more information about the entity types eligible to participate in the 340B program.)

To examine how manufacturers' distribution of drugs at 340B prices affects providers' access to drugs, whether those providers are covered entities or non-340B providers, we conducted interviews with 61 340B program stakeholders, including our judgmental sample of 29 covered entities, as well as 32 other program stakeholders representing a wide range of perspectives on the program.¹⁸ Included were interviews with 6 drug manufacturers, selected based on factors such as having a large market share and producing drugs with reported challenges related to their distribution at 340B prices, and 6 organizations representing drug manufacturers and others involved in distributing drugs from manufacturers to providers. We also interviewed stakeholders representing providers, including 9 organizations representing covered entities, 2 organizations representing non-340B providers, and 5 organizations representing both covered entities and non-340B providers. Finally, we interviewed HRSA and the Centers for Medicare & Medicaid Services (CMS), as well as HRSA's 2 340B program contractors. (See appendix I for more details on interviewees and how we selected them.) Similar to our selection of covered entities, our selection of other program stakeholders was judgmental and, as such, responses are not generalizable. In addition, we reviewed relevant documentation from interviewees, and analyzed industry data as well as data from HRSA's covered entity database to determine the number of hospitals in the U.S. currently participating in the 340B program. We reviewed data-related documentation and interviewed agency officials, and determined these data were sufficiently reliable for our purposes.

To examine HRSA's oversight of the 340B program, we conducted interviews with the 61 program stakeholders discussed above and reviewed relevant documentation. We reviewed information from HRSA and other HHS agencies, including those that administer the grants that

¹⁸We conducted multiple interviews with certain organizations for a total of 65 interviews.

make entities eligible for the 340B program.¹⁹ We also reviewed key laws, guidance, and relevant literature related to the program and to safety net providers. We analyzed data from HRSA's covered entity database to determine changes in 340B program participation among covered entity types since 2001. We reviewed data-related documentation and interviewed agency officials, and determined these data were sufficiently reliable for our purposes.

We conducted our performance audit from September 2010 through September 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The 340B program was created in 1992 following the enactment of the Medicaid Drug Rebate Program and gives certain safety net providers discounts on outpatient drugs comparable to those made available to state Medicaid agencies.²⁰ HRSA, through its Office of Pharmacy Affairs, is responsible for administering and overseeing the 340B program,²¹ which according to federal standards, includes designing and implementing necessary policies and procedures to enforce agency objectives and assess program risk. These policies and procedures include internal controls that provide reasonable assurance that an

¹⁹HHS agencies that administer the grants that make entities eligible for the 340B program include HRSA, Indian Health Services, Office of Population Affairs, and the Centers for Disease Control and Prevention. CMS calculates Medicare DSH adjustment percentages for hospitals.

²⁰The Medicaid Drug Rebate Program was established through the Omnibus Budget Reconciliation Act of 1990 and requires drug manufacturers to pay rebates to states as a condition of having their drugs covered by Medicaid. Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (adding 42 U.S.C. § 1396r-8).

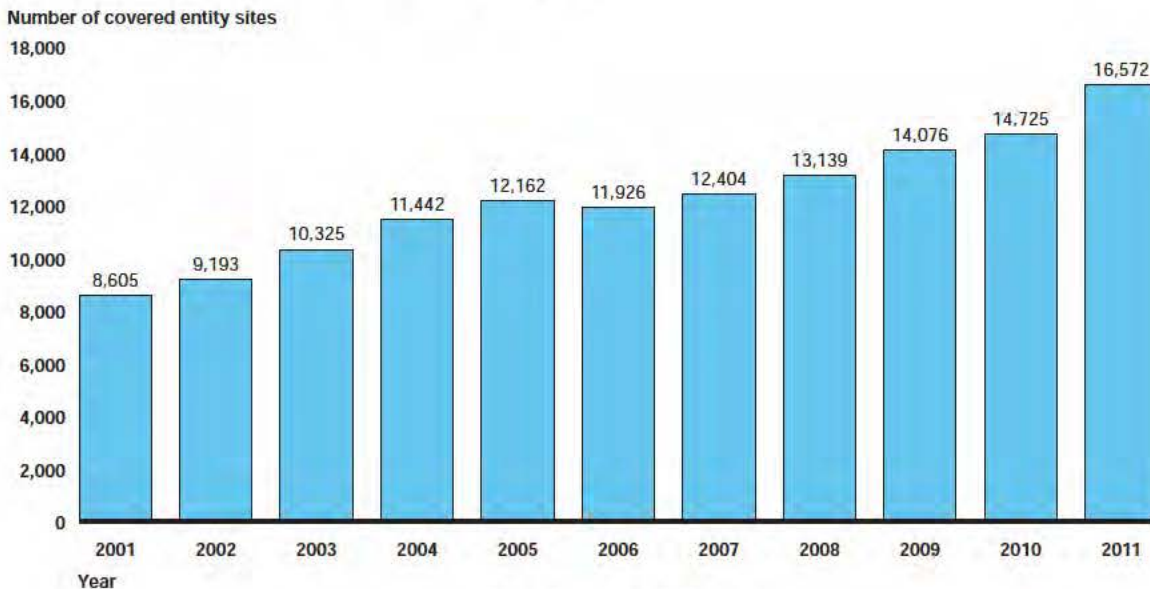
²¹The Pharmacy Services Support Center (PSSC) and the Prime Vendor Program (PVP) assist HRSA with the administration of the 340B program and are managed by contractors. The PSSC provides guidance and free technical assistance to covered entities and helps ensure that patients of covered entities receive comprehensive pharmacy services. The PVP establishes a distribution network for pharmaceuticals to covered entities and negotiates prices for a portfolio of drugs below the 340B price. Participation in the PVP is free and voluntary for covered entities.

agency has effective and efficient operations and that program participants are in compliance with applicable laws and regulations.²²

Program Participants

Eligibility for the 340B program is defined in the PHSA. Entities generally become eligible by receiving one of 10 federal grants or by being one of six hospital types. (See appendix II for a complete list of covered entity types and their eligibility requirements.) To participate in the 340B program, eligible entities must register with HRSA and be approved. Entity participation in the 340B program has grown over time to include over 16,500 covered entity sites (see fig. 1).

Figure 1: Growth in Covered Entity Sites, 2001 to 2011



Source: GAO analysis of HRSA data.

²²See GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999).

Federal grantees are eligible for the 340B program by virtue of receiving certain federal grants administered by different agencies within HHS. Eligible grantees include clinics that offer primary and preventive care services, such as FQHCs,²³ family planning clinics, and clinics that target specific conditions or diseases that raise public health concerns or are expensive to treat, such as hemophilia treatment centers. Participating clinics may offer eligible services at one or multiple sites. They also include state-operated ADAPs, which serve as a “payer of last resort” to cover the cost of providing HIV-related medications to certain low-income individuals.

Hospitals eligible for the 340B program include certain DSH hospitals, children’s hospitals, freestanding cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals. While DSH hospitals have been eligible for the program since its inception, children’s hospitals became eligible in 2006, and the remaining hospital types became eligible through PPACA.²⁴

Hospital eligibility for the 340B program has more elements than that of federal grantees, because unlike federal grantees, hospitals do not qualify for the program based on receipt of a federal grant. Rather, they must meet certain requirements intended to ensure that they perform a government function to provide care to the medically underserved. First, hospitals generally must meet specified DSH adjustment percentages to qualify; however, critical access hospitals are exempt from this requirement.²⁵ Additionally, all hospitals must be (1) owned or operated

²³Not all FQHCs receive federal grants. Providers that meet all of the requirements for the FQHC program but do not receive federal grants are referred to as FQHC look-alikes and are eligible to participate in the 340B program.

²⁴See Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302, 124 Stat. 1029, 1082. While PPACA explicitly added children’s hospitals to the list of covered entities under the 340B program in the PHSA, they were originally made eligible under the Social Security Act through the Deficit Reduction Act of 2005. Pub. L. No. 109-171, § 6004, 120 Stat. 4, 61 (2006) (amending 42 U.S.C. § 1396r-8(a)(5)(B)).

²⁵To be eligible for the 340B program, rural referral centers and sole community hospitals must have a DSH adjustment percentage that is equal to or greater than 8 percent, and DSH, children’s, and free-standing cancer hospitals must have a DSH adjustment percentage that is greater than 11.75 percent. Although children’s and free-standing cancer hospitals do not receive payments under the Medicare inpatient prospective payment system, they must have a payer mix that would result in a DSH adjustment percentage of greater than 11.75 percent.

by a state or local government, (2) a public or private, nonprofit corporation that is formally delegated governmental powers by a unit of state or local government,²⁶ or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low income individuals who are not eligible for Medicaid or Medicare. Clinics and other sites affiliated with a hospital, but not located in the main hospital building, are eligible to participate in the 340B program if they are an integral part of the hospital, which HRSA has defined as reimbursable sites on the hospital's most recently filed Medicare cost report.²⁷

All drug manufacturers that supply outpatient drugs are eligible to participate in the 340B program and must participate if they want their drugs covered by Medicaid. To participate, manufacturers are required to sign a pharmaceutical pricing agreement with HHS in which both parties agree to certain terms and conditions and submit this agreement to HRSA.

Program Structure and Operation

Covered entities typically purchase and dispense 340B drugs through pharmacies and can structure their programs in different ways. Entities can have (1) an in-house pharmacy model, in which the pharmacy is housed within the covered entity, (2) a contract pharmacy model, in which the entity contracts with an outside pharmacy to dispense drugs on their behalf, or (3) both. Historically, only covered entities that did not have an in-house pharmacy were allowed to contract with a single outside pharmacy to provide services. In March 2010, however, HRSA issued guidance allowing all covered entities—including those that have an in-house pharmacy—to contract with multiple outside pharmacies.²⁸ Some covered entities use HRSA's Pharmacy Services Support Center (PSSC) or private companies that provide technical assistance, information

²⁶According to HRSA, a hospital is said to be "formally granted governmental powers" when the state formally delegates to the hospital a type of power(s) usually exercised by the state, for the purpose of providing health care services to the medically indigent population of the state.

²⁷Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Outpatient Hospital Facilities, 59 Fed. Reg. 180, 47884 (Sept. 19, 1994).

²⁸Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (March 5, 2010).

technology, and other services to help develop, implement, and manage their 340B pharmacy program.

The 340B price for a drug—often referred to as the 340B ceiling price—is based on a statutory formula and represents the highest price a drug manufacturer may charge covered entities;²⁹ however, the provision establishing the 340B pricing formula indicates that manufacturers may sell a drug at a price that is lower than the ceiling price.³⁰ As such, covered entities may negotiate prices below the ceiling price. Manufacturers are responsible for calculating the 340B price on a quarterly basis. Occasionally the formula results in a negative price for a 340B drug.³¹ In these cases, HRSA has instructed manufacturers to set the price for that drug at a penny for that quarter—referred to as HRSA’s penny pricing policy.

Key Program Requirements

Covered entities must follow certain program requirements as a condition of participating in the 340B program. For example, covered entities are prohibited from diverting any drug purchased at a 340B price to an individual who does not meet HRSA’s current definition of a patient. This definition was issued in 1996 and outlines three criteria which generally state that diversion occurs when 340B discounted drugs are given to individuals who are not receiving health care services from covered entities or are only receiving non-covered services, such as inpatient hospital services, from covered entities. (See table 1 for more information on HRSA’s definition of a 340B patient.) Covered entities are permitted to use drugs purchased at the 340B price for all individuals who meet the definition of a patient, whether or not they are low income, uninsured, or underinsured.

²⁹In general, the 340B price for a drug is calculated quarterly by subtracting the unit rebate amount used in the Medicaid Drug Rebate Program from the drug’s average manufacturer price. See 42 U.S.C. § 256b (a)(1). Average manufacturer price is the average price paid to a manufacturer for drugs distributed to retail community pharmacies. It includes direct manufacturer sales to retail community pharmacies, as well as sales by wholesalers. 42 U.S.C. §§ 256b(b), 1396r-8(k).

³⁰42 U.S.C. § 256b(a)(10).

³¹When a drug’s average manufacturer price increases more quickly than the rate of inflation, the government requires the manufacturer to pay an additional rebate amount. This may cause the drug’s unit rebate amount to be greater than the drug’s average manufacturer price, which would result in a negative 340B price.

Table 1: HRSA’s Definition of a Patient Eligible for Discounted Drugs under the 340B Program

Criteria for patient eligibility^a

1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care.
 2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity.^b
 3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or FQHC look-alike status has been provided.^c
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Source: GAO analysis of HRSA guidance.

Notes: HRSA guidance on the definition of a patient eligible for discounted drugs under the 340B program was issued in 1996. See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 207, 55156 (Oct. 24, 1996).

^aThese criteria do not apply to ADAPs; rather, an individual will be considered a patient of an ADAP if enrolled in the ADAP program.

^bAn individual is not considered a patient if the only health care service received from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

^cDSH hospitals are exempt from this requirement.

Covered entities also are prohibited from subjecting manufacturers to duplicate discounts whereby drugs prescribed to Medicaid patients are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program. To avoid duplicate discounts, covered entities can either purchase drugs for Medicaid patients outside the 340B program, in which case the state Medicaid agency may claim the rebate, or they can use drugs purchased at 340B prices, in which case the agency may not claim the rebate. Covered entities that decide to use 340B drugs for Medicaid patients must notify HRSA so that it can coordinate with state Medicaid agencies for billing purposes. Further, certain covered entities—DSH hospitals, children’s hospitals, and freestanding cancer hospitals—are prohibited from purchasing outpatient drugs through any group purchasing organization (GPO).³² However, they may purchase drugs through the specified HRSA contractor, the Prime Vendor Program (PVP). Rural referral centers, sole community hospitals, and critical

³²GPOs contract with providers, such as hospitals, and, on behalf of their members, aggregate purchasing volume to negotiate discounts on drugs from drug manufacturers or distributors.

access hospitals participating in the 340B program are allowed to purchase outpatient drugs through any GPO.

Drug manufacturers also must follow certain 340B program requirements. Specifically, they must sell outpatient drugs to covered entities at or below the statutorily determined price. In addition, HRSA's nondiscrimination guidance prohibits manufacturers from distributing drugs in ways that discriminate against covered entities compared to other providers. This includes ensuring that drugs are made available to covered entities through the same avenue that they are made available to non-340B providers, and not conditioning the sale of drugs to covered entities on restrictive conditions, which would have the effect of discouraging participation in the 340B program.

340B Revenue Generated by Covered Entities Varied, but All Entities Reported That the Program Was Used to Support or Expand Access to Services

About half of the covered entities we interviewed reported that they generated 340B program revenue that exceeded drug-related costs—the costs of purchasing and dispensing a drug—and revenue generation depended on several factors. Regardless of the amount of 340B revenue generated or the savings realized through 340B discounts, covered entities generally reported using the 340B program to support or expand access to services.

About Half of Covered Entities Reported Generating 340B Revenue That Exceeded Drug-Related Costs, and Revenue Generated Depended on Several Factors

Thirteen of the 29 covered entities we interviewed reported that they generated revenue through the 340B program that exceeded drug-related costs.³³ Of the 16 remaining, 10 did not generate enough 340B revenue to cover all drug-related costs, and 6 covered entities were unable or did not report enough information for us to determine the extent to which they generated 340B revenue due, in part, to their inability to track 340B-specific financial information.

In general, 340B revenue—whether exceeding drug related costs or not—was generated through reimbursement received for drugs dispensed by 340B in-house or contract pharmacies, though several factors affected the extent to which the covered entities we interviewed generated revenue through the program:³⁴

- **Third-party reimbursement rates:** Eighteen of the 29 covered entities we interviewed generated 340B revenue by receiving reimbursement from third-party payers and tracked revenue by payer source. Of the 18, most reported that they generated more 340B revenue from patients with private insurance and Medicare compared to other payers.³⁵ However, a few of these covered entities reported that their ability to generate 340B revenue from private insurers, including Medicare Part D plans, was decreasing because some insurers were reducing contracted reimbursement rates for drugs based on the entity's status as a 340B provider. Of the 18 covered entities, most of those that used 340B drugs for Medicaid patients reported that state-determined Medicaid reimbursement rates for these drugs were generally lower, compared to private insurers and Medicare. For example, most reported that Medicaid reimbursement for a 340B drug was set at the price paid for the drug—the 340B price

³³For this report, we define 340B revenue as all monies received by covered entities for drugs they purchase at the 340B price, whether or not the revenue meets or exceeds the costs paid for the drugs. When data provided by covered entities was used to determine revenue generation, the most recent year of reported data was used.

³⁴Even though 6 covered entities were unable to report the amount of revenue they generated through the program, they were able to report what factors affected overall revenue generation.

³⁵Medicare reimburses outpatient prescription drugs either through Medicare Part B or Part D. Part B covers drugs administered by physicians, such as chemotherapy drugs, and payment for those drugs is set by a fee schedule established quarterly by CMS. Part D sponsors are typically private insurers that contract with CMS to cover outpatient prescription drugs and negotiate reimbursement rates directly with health care providers.

or any lower price—plus a dispensing fee, the latter of which generally did not cover the costs of dispensing the drug.³⁶ This is typically referred to as reimbursement at actual acquisition cost, which reduces a covered entity's ability to generate revenue because the state, rather than the entity, benefits from any savings from purchasing drugs at the 340B price.³⁷ However, a few covered entities generated more 340B revenue through Medicaid than others because they had contractual agreements with their states to share 340B-related savings.³⁸ Covered entities in two of the five states included in our selection had such agreements. Finally, a majority of the 18 covered entities reported that revenue generated from uninsured patients was lower than that from all other payers.

- **ADAP status:** Factors that affected 340B revenue generation for the five ADAPs we interviewed were different than for other entity types, because unlike other covered entity types, ADAPs do not receive third-party reimbursement for drugs. Rather, ADAPs serve as a “payer of last resort” to cover the cost of providing HIV-related medications to certain low-income individuals who, for example, are uninsured and cannot afford to pay for drugs or who cannot afford their health insurance coverage for drugs. ADAPs can choose to cover costs of drugs by either paying for the drugs directly or by assisting patients with the costs associated with health insurance, including payments for premiums and co-payments or deductibles. When ADAPs purchase drugs directly, they realize 340B savings on drugs—either at the point of purchase or after the fact through manufacturer rebates—but do not generate revenue through the program. When ADAPs assist with patients' health insurance by paying for co-payments or

³⁶A dispensing fee is typically a set dollar amount per prescription that covers the overhead costs of dispensing a drug, such as pharmacy staff time.

³⁷State Medicaid agencies may reimburse entities at actual acquisition cost, because when entities decide to use drugs purchased at 340B prices for Medicaid patients, the state can no longer claim Medicaid rebates for those drugs.

³⁸These contractual agreements are commonly referred to as shared savings agreements. Shared savings agreements provide covered entities reimbursement above actual acquisition cost, for example, by paying a higher dispensing fee to covered entities than the fee paid to other providers. According to the HHS Office of Inspector General, states may be interested in shared savings agreements with covered entities because 340B prices can be considerably lower than states' standard Medicaid reimbursement rates and entering into such agreements could encourage entities to use 340B drugs for Medicaid patients while still saving money for states.

deductibles on a drug, they sometimes generate revenue by collecting the rebates representing the full 340B discount on a drug for which they may have only paid a portion of the price. Three of the five ADAPs we interviewed reported generating revenue this way.

- **Ability to leverage resources to access the lowest drug prices:** Some of the 29 covered entities we interviewed reported leveraging resources, such as through their larger parent organizations or the PVP, to access drugs at prices below the 340B ceiling price, potentially increasing the difference between the price paid for the drug and the reimbursement received. In addition, some covered entities said they had access to sophisticated information technology—for example by contracting with private companies—or had more staff to help ensure that they were obtaining the lowest priced drugs.

As more people gain insurance coverage under PPACA, covered entities may serve more patients with private insurance and Medicaid,³⁹ which may affect the extent to which they generate 340B revenue. One covered entity located in Massachusetts reported that after the state implemented universal health care, while they received more revenue from reimbursement for low-income patients that gained private insurance, these patients often could not afford associated co-payments or deductibles, and the entity covered these costs.⁴⁰ In addition, according to one ADAP we interviewed, as more individuals gain private insurance, the ADAP may increasingly choose to pay for health insurance for patients rather than paying for patients' drugs directly. This may enable it to generate revenue through the 340B program if it can claim more rebates for drugs for the newly insured patients. According to some covered entities, the impact of serving more Medicaid patients may depend on the Medicaid reimbursement rate that entities receive. For example, patients that gain Medicaid coverage may begin to seek services from covered entities, and for those entities that lose money on Medicaid patients, this may decrease their ability to generate 340B revenue. Conversely, for covered entities that have contractual agreements to share 340B-related

³⁹PPACA contains provisions to expand private health insurance and Medicaid coverage to more Americans. See, e.g., Pub. L. No. 111-148, § 2001, 124 Stat. 119, 271.

⁴⁰HRSA officials told us that this statement is consistent with their belief that low-income patients will continue to require assistance with health care costs after gaining insurance.

savings with their states, the increased Medicaid population may increase their ability to generate 340B revenue.

Covered Entities Reported Using the 340B Program to Support or Expand Access to Services

Regardless of the amount of revenue generated through the program, all of the 29 covered entities we interviewed reported that the 340B program, including the up-front savings they realized on the cost of drugs, allowed them to support their missions by maintaining services and lowering medication costs for patients, which is consistent with the purpose of the program. For example, some covered entities reported that they used the 340B revenue generated by certain patients to offset losses incurred from other patients, which helped support the financial stability of the organization and allowed them to maintain services. Further, one covered entity reported that without 340B revenue or the savings on drugs through its participation in the program, it would be unable to offer all the services it provides—both pharmaceutical and clinical—and another reported that it would have to close its outpatient pharmacy without the program. In addition to maintaining services, some covered entities passed 340B savings on to patients by providing lower-cost drugs to uninsured patients. For example, many covered entities determined the amount that a patient is required to pay based on the lower cost of 340B-priced drugs.

In addition, the 13 covered entities that generated 340B revenue that exceeded drug-related costs were able to use this revenue to serve more patients and to provide services that they might not have otherwise provided, including additional service locations, patient education programs, and case management, which is also consistent with the purpose of program. One covered entity, for example, reported that it used the revenue generated through the 340B program to provide additional service delivery sites in other parts of the state, which eliminated the need for some patients to travel more than 60 miles to receive services. A few covered entities reported using 340B revenue to support patient and family education programs, such as those where pharmacists provide education on drug interactions. Additionally, one covered entity reported using 340B program revenue to fund a case management program that did not generate any revenue on its own;⁴¹ some services provided through this program included arranging

⁴¹Case management services facilitate access to appropriate health care, and are not typically reimbursed by payers.

transportation for patients to receive clinical services, coordinating necessary specialty care, and providing translation services.

Even though the uses of revenue generated through the 340B program were for similar purposes, some covered entities relied on the program more than others. For example, one FQHC reported that 340B revenue accounted for approximately 5 percent of its total budget, and was used to provide additional services within the organization. However, one hemophilia treatment center reported that 340B revenue accounted for about 97 percent of its total budget and was used to support all of its program operations.⁴²

Manufacturers’ Distribution of Drugs at 340B Prices Generally Did Not Affect Providers’ Access to Drugs Except in Two Situations

According to stakeholders we interviewed, manufacturers’ distribution of drugs at 340B prices generally did not affect providers’ access to drugs. For example, 36 of the 61 program stakeholders we interviewed did not report any effect on covered entities’ or non-340B providers’ access to drugs related to manufacturers’ distribution of drugs at 340B prices. These stakeholders represented a wide range of perspectives on the 340B program, including those representing manufacturers, covered entities, and non-340B providers.

The remaining 25 program stakeholders—also representing a wide range of perspectives on the 340B program—reported that manufacturers’ distribution of drugs at 340B prices affected providers’ access to drugs primarily in two situations.⁴³ The two situations were: (1) for intravenous immune globulin (IVIG), a lifesaving immune deficiency drug, the supply

⁴²The organizational structure of hemophilia treatment centers we interviewed varied, and those that operated stand-alone programs were more dependent on 340B revenue than those that were integrated into hospitals.

⁴³While stakeholders consistently reported two situations in which manufacturers’ distribution of drugs at 340B prices affected providers’ access to these drugs, some, such as covered entities, reported other situations that had effects on access, but it was not clear that the other situations were related to manufacturers’ distribution of drugs at 340B prices.

of which is inherently limited;⁴⁴ and (2) when there was a significant drop in the 340B price of a drug, which may result in increased demand for the drug by covered entities. Both situations relate to the restricted distribution of drugs, which may occur during shortages or when shortages are anticipated.

Stakeholders reported that manufacturers' restricted distribution of IVIG at 340B prices resulted in 340B hospitals having to purchase some IVIG at higher, non-340B prices in order to meet their demand for the drug.⁴⁵ Manufacturers restrict the distribution of IVIG on an ongoing basis, because it is susceptible to shortages. Stakeholders, including five of the seven DSH hospitals we interviewed, reported that because of the restricted distribution of IVIG at 340B prices, 340B hospitals often must purchase some IVIG at higher, non-340B prices to meet their patients' needs. For example, DSH hospitals reported that when they were unable to access IVIG at 340B prices, additional IVIG was available for purchase at higher, non-340B prices directly from manufacturers, from specialty pharmacies,⁴⁶ or from GPOs.⁴⁷ Moreover, one DSH hospital reported that it had to purchase about one-third of the IVIG it needed at non-340B

⁴⁴IVIG is primarily used to treat patients with immune deficiency diseases, a group of disorders in which the immune system fails to produce enough antibodies, thereby predisposing individuals to increased risk of infection. Factors inherent to the development and distribution of IVIG limit its supply making it susceptible to shortages, including that IVIG is made from human plasma, which is an inherently scarce resource, and that IVIG takes between seven and 12 months to manufacture. Additionally, only a few manufacturers develop and distribute these drugs in the United States.

⁴⁵Hospitals are the primary purchaser of IVIG in the United States.

⁴⁶Specialty pharmacies handle and distribute drugs that, among other things, have a high acquisition cost and require special handling practices.

⁴⁷In general, 340B hospitals are prohibited from purchasing outpatient drugs through GPOs. While no DSH hospital we interviewed reported purchasing IVIG through GPOs, GPOs we interviewed told us that 340B hospitals have purchased IVIG through this avenue when they are unable to access it at the 340B price. During a December 2005 congressional hearing on the 340B program, an organization representing 340B hospitals argued that in situations when hospitals are unable to purchase IVIG at 340B prices, they are faced with either violating federal law by purchasing IVIG through GPOs, buying IVIG at cost-prohibitive retail prices, or denying their patients access to these drugs. See "Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency," Hearing before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, December 15, 2005. While 340B hospitals can receive the benefits of group purchasing through the PVP, the PVP does not have any contracts for IVIG.

prices—paying about \$20,000 to \$25,000 more per month than what it would have paid if it could have purchased it at 340B prices.

Although manufacturers' distribution of IVIG at 340B prices may not meet 340B hospitals' demand, some stakeholders, such as drug manufacturers, reported that changes in the amount of IVIG allocated for sale at 340B prices could negatively affect non-340B providers' access to these drugs. For example, one IVIG manufacturer reported that it restricted its distribution of IVIG by allocating its supply based on the amount of the drug purchased by providers in 2004—allocating 95 percent of its projected monthly sales to non-340B providers and the remaining 5 percent to covered entities at the 340B price.⁴⁸ This manufacturer stated that its distribution was fair, and that changing distribution plans to increase the amount of IVIG drugs available at 340B prices could negatively affect non-340B providers' access to the drugs. However, HRSA officials told us that the allocation of IVIG in this way is not sufficient or fair. Nearly a third of the nation's hospitals currently participate in the 340B program, and one large GPO we interviewed reported that 340B hospitals tended to be the bigger hospitals in the company's membership base.⁴⁹ Thus, if other manufacturers similarly restrict the distribution of IVIG at 340B prices, it is unlikely that covered entities' demands will be met at the 340B price.⁵⁰

Stakeholders reported that manufacturers' distribution of drugs at 340B prices also affected providers' access to drugs when the 340B prices dropped significantly. In certain cases, when the 340B price of a drug dropped, some covered entities stockpiled the drug, which resulted in shortages in the supply for other providers, including other covered entities. For example, two covered entities we interviewed reported challenges accessing drugs when their 340B prices dropped, because other entities purchased large amounts of these drugs. In other cases

⁴⁸This manufacturer reported that it based its allocation of IVIG on 2004 purchasing patterns, because this was the last period before demand exceeded supply for the product and an allocation system became necessary. While data on the number of hospitals participating in the 340B program in 2004 are not available, the number of 340B hospitals has grown from 591 in 2005 to 1,673 in 2011.

⁴⁹While certain 340B hospitals are prohibited from purchasing outpatient drugs through GPOs, all 340B hospitals can purchase inpatient drugs through GPOs.

⁵⁰The Department of Justice is examining the IVIG market in the United States, in part, due to concerns about the distribution of these drugs at 340B prices.

when the 340B prices dropped, manufacturers restricted the distribution of those drugs at 340B prices to ensure that all providers had equitable access. For example, one manufacturer reported that after the price of an oral contraceptive dropped to a penny as a result of HRSA's penny pricing policy, it received an order from a covered entity that exceeded the manufacturer's current national supply by 50 percent. In response, this manufacturer consulted with HRSA to ensure compliance with the agency's nondiscrimination guidance and restricted the distribution of drugs at 340B prices by allocating its supply based on the projected demand in the market and providers' past purchasing patterns.

HRSA's Oversight of the 340B Program Is Inadequate

HRSA's oversight of the 340B program is inadequate because it primarily relies on participants' self-policing to ensure compliance. Changes in the settings where the program is used may heighten concerns about the inadequacy of HRSA's oversight, and HRSA's plans for improving oversight are uncertain.

HRSA's Oversight Is Inadequate to Ensure Participants' Compliance with 340B Program Requirements

HRSA's oversight of the 340B program is inadequate because it primarily relies on covered entities' and manufacturers' self-policing—that is, participants ensuring their own compliance with program requirements. Upon enrollment, HRSA requires both covered entities and manufacturers to certify that they will comply with applicable 340B program requirements and any accompanying agency guidance. As part of this certification, agency officials told us that they expect participants to develop the procedures necessary to ensure compliance, maintain auditable records that demonstrate compliance, and inform HRSA if violations occur. For example, covered entities must develop adequate safeguards to prevent drugs purchased at 340B prices from being diverted to non-eligible patients, such as inventory tracking systems that separately purchase and dispense 340B drugs, and manufacturers must ensure that they properly calculate the 340B price of their drugs. In both cases, program participants must keep auditable records that can show that they have complied with program requirements and produce that documentation if requested by HRSA.

HRSA officials told us that covered entities and manufacturers can also monitor each other's compliance with program requirements, but in practice, participants may face limitations to doing so. For example, two covered entities we interviewed reported that it is difficult to determine whether they have been charged correctly for drugs because manufacturers' calculations of 340B prices are not transparent—namely,

there is no centralized list of 340B prices.⁵¹ An organization representing covered entities also told us that its members had reported this difficulty. Similarly, three drug manufacturers we interviewed reported that, although they sometimes have suspected covered entities of diverting 340B drugs, it is difficult to prove diversion took place. An organization representing some manufacturers explained that, although manufacturers have the authority to audit covered entities, they have only conducted them in egregious circumstances, because agency requirements for these audits—such as a requirement to hire an independent third party to conduct the audits—are costly and administratively burdensome.

HRSA's guidance on key program requirements often lacks the necessary level of specificity to provide clear direction, making it difficult for participants to self-police or monitor others' compliance and raising concerns that the guidance may be interpreted in ways that are inconsistent with its intent.⁵² For example, HRSA's current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for the purposes of 340B and thus, covered entities could interpret it either too broadly or too narrowly. Stakeholders we interviewed, including those representing covered entities and drug manufacturers, raised concerns that the guidance will be interpreted too broadly leading to cases of unintended diversion—that is, using 340B drugs for individuals who HRSA did not intend as eligible patients, but who may not be clearly prohibited in the guidance. However, one of these stakeholders representing covered entities also noted that, in order to ensure compliance, some entities may adhere to a narrow interpretation of the guidance and thus, limit the benefit of the program for their organization. The agency itself has recognized the need to further specify the definition of a 340B patient to ensure that it is interpreted correctly.

⁵¹Prior to PPACA, covered entities did not have access to 340B pricing data in order to monitor manufacturers because the Social Security Act prohibited the disclosure of the data by HRSA and state Medicaid agencies. 42 U.S.C. § 1396r-8(b)(3)(D). PPACA added a provision to Section 340B requiring that covered entities be allowed access to 340B pricing data. Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 824 (adding 42 U.S.C. § 256b(d)(1)(iii)).

⁵²In May 2011, HRSA published its first proposed regulation on the 340B program, Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program, 76 Fed. Reg. 29, 183 (proposed May 20, 2011). Until this point the agency had provided program guidance through notices published in the Federal Register, which were typically finalized after a notice and comment period, as well as more informal guidance on its web site.

For example, HRSA officials told us that the definition currently includes individuals receiving health care services from providers affiliated with covered entities through “other arrangements,” as long as the responsibility for care provided remains with the entity. However, HRSA does not define “other arrangements,” and officials told us that what is meant by responsibility for care also needs to be clarified. As a result of the lack of specificity in the guidance, the agency has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity is serving an administrative function and does not actually have the responsibility for care.

In addition, HRSA has not issued guidance specifying the criteria under which hospitals that are not publicly owned or operated can qualify for the 340B program.⁵³ Rather, the agency bases eligibility for these hospitals on the application of broad statutory requirements that they are either formally delegated governmental powers by a unit of a state or local government or have a contract with a state or local government to provide services to low-income individuals who are not eligible for Medicaid or Medicare. HRSA has stated that the determination of whether hospitals meet the first requirement is evaluated by the agency on a case-by-case basis. For the second requirement, HRSA requires a state or local government official and a hospital executive to certify that a contract exists to meet the requirement, but does not require hospitals to submit their contracts for review or outline any criteria that must be included in the contracts, including the amount of care a hospital must provide to these low-income individuals.⁵⁴ Therefore, hospitals with contracts that provide a small amount of care to low-income individuals not eligible for Medicaid or Medicare could claim 340B discounts, which may not be what the agency intended.

⁵³We use the term hospitals that are not publicly owned or operated to refer to public and private, nonprofit corporations as well as private, nonprofit hospitals that may be eligible for the 340B program. The term does not include private, for-profit hospitals as these hospitals are not eligible for the 340B program.

⁵⁴HRSA officials told us that contracts are selectively reviewed if further clarification is necessary.

Moreover, HRSA's nondiscrimination guidance is not specific in the practices that manufacturers should follow to ensure that drugs are equitably distributed to covered entities and non-340B providers when distribution is restricted. Some stakeholders we interviewed, such as covered entities, have raised concerns about the way IVIG manufacturers have interpreted and complied with the guidance in these cases, because covered entities have sometimes had to purchase IVIG at higher, non-340B prices. Additionally, given current guidance, one stakeholder reported that manufacturers can offer a certain amount of drugs at 340B prices, and while the distribution may not be equitable, still contend that they are complying with the guidance. Although PPACA included a provision prohibiting manufacturers from discriminating against covered entities in the sale of 340B drugs, officials told us they do not have plans to provide any additional specificity to the nondiscrimination guidance.

Finally, in the case of HRSA's penny pricing policy, agency officials told us that it is well understood by 340B stakeholders and manufacturers we interviewed were generally aware of the policy. However, the agency has never formalized guidance in writing and there have been documented cases of manufacturers charging covered entities more than a penny for drugs when the policy should have been in effect.⁵⁵

Beyond relying on participants' self-policing, HRSA engages in few activities to oversee the 340B program and ensure its integrity, which agency officials said was primarily due to funding constraints. For example, HRSA officials told us that the agency verifies eligibility for the 340B program at enrollment, but does not periodically recertify eligibility

⁵⁵In a 2006 report, the HHS Office of Inspector General found that manufacturers did not always follow HRSA's penny pricing policy. Both in this report and in a 2005 report, the Office of Inspector General recommended that HRSA formalize its penny pricing policy in writing. See HHS Office of Inspector General, *Review of 340B Prices*, OEI-05-02-00073 (Washington, D.C.: 2006); and HHS Office of Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072 (Washington, D.C.: 2005).

for all covered entity types.⁵⁶ As a result, there is the potential for ineligible entities to remain enrolled in the program. In addition, HRSA officials told us that they do not require a review of the procedures participants put in place to ensure compliance, and, although the agency has the authority to conduct audits of program participants to determine whether violations have occurred, it has never done so.⁵⁷ For example, officials said that they do not verify whether covered entities have systems in place to prevent diversion. Also, while HRSA encourages manufacturers to work with the agency to develop processes for restricting the distribution of drugs that are equitable to covered entities and non-340B providers, the agency only reviews manufacturers' plans to restrict access to drugs at 340B prices if a manufacturer contacts HRSA or concerns with a plan are brought to the agency's attention. Similarly, although HRSA calculates 340B prices separately from manufacturers, officials told us that, at this time, the agency does not use these calculations to verify the price that manufacturers charge covered entities, unless an entity reports a specific pricing concern.⁵⁸

HRSA's oversight activities are further limited because the agency lacks effective mechanisms to resolve suspected violations and enforce program requirements when situations of non-compliance occur. If covered entities and manufacturers are not able to resolve conflicts on their own, HRSA has had an informal dispute resolution process in place since 1996 through which program participants can request that HRSA

⁵⁶HRSA currently recertifies eligibility for sexually transmitted diseases, tuberculosis, and Ryan White grantees, consistent with requirements under the PHSA. In addition, HRSA verifies the grantee status of FQHCs as well as hospitals' DSH percentages on a quarterly basis. As resources allowed, HRSA has also periodically recertified 340B eligibility for other entity types. For example, HRSA recertified eligibility for family planning clinics in 2010. PPACA added a provision requiring HRSA to conduct annual recertification of eligibility for all covered entity types. HRSA officials told us that the Office of Pharmacy Affairs' fiscal year 2011 budget allowed for the planning of a phased approach to recertification of all entity types, which is scheduled to begin in the fall of 2011. As of August 2011, officials were not able to tell us which entity types would be phased in first.

⁵⁷HRSA officials told us that while they do not conduct audits, if a potential violation of program requirements is brought to their attention, they will refer the matter to the HHS Office of Inspector General. Officials said that they have made two such referrals in the past year related to the diversion of 340B drugs.

⁵⁸HRSA previously operated a voluntary pilot program with manufacturers to improve the integrity of 340B pricing calculations. Twelve manufacturers participated in the program, which was discontinued in March 2008 due to concerns regarding the confidentiality of drug pricing data and a lack of funding to run the program.

review evidence of a suspected violation and the agency then decides whether to initiate the process. However, despite reports by program participants about suspected violations they were unable to resolve on their own, HRSA officials told us that they have only initiated the dispute resolution process twice since its inception.⁵⁹ Additionally, HRSA has not issued regulations implementing monetary penalties for non-compliance established by PPACA, and HRSA has rarely utilized the sanctions that existed prior to PPACA. For example, participants found to be in violation of 340B program requirements face termination from the program. Yet according to HRSA officials, since the program's inception, only two covered entities have been terminated from the program due to findings of program violations and no manufacturer has ever been terminated for this reason.⁶⁰ Covered entities also are expected to pay back manufacturers for discounts received while out of compliance, and manufacturers are expected to pay back covered entities for overcharges. However, HRSA has not enforced these expectations and officials were unable to tell us the extent to which repayments have occurred.

Because of HRSA's reliance on self-policing to oversee the 340B program as well as its nonspecific guidance, the agency cannot provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements and is not able to adequately assess program risk. As a result, covered entities may be inappropriately

⁵⁹For example, a covered entity we interviewed said that it suspected certain drug manufacturers of implementing strategies to avoid offering drugs at correct 340B prices, but because of the lack of transparency in how 340B prices are calculated, could not determine this on its own. According to the entity, when it contacted HRSA about these strategies, agency officials said that they did not have the resources to help. However, HRSA officials told us that they were unaware of any instances where the agency has not helped a covered entity under these circumstances. Officials from one manufacturer reported that it provided HRSA with evidence that a covered entity had engaged in multiple instances of diversion, and after attempting to resolve the instances with the entity on its own, requested a hearing through the dispute resolution process in January of 2010. HRSA officials told us that the agency dismissed the manufacturer's request to initiate the process, because the covered entity disputed the manufacturer's claim that it had attempted to resolve the issue on its own, and that the agency is currently considering the manufacturer's appeal of this dismissal.

⁶⁰In a 2005 report on the 340B program, the HHS Office of Inspector General noted that terminating a manufacturer from the 340B program also means that the manufacturer would be terminated from the Medicaid program, making it a difficult sanction to put into practice, given the effects on access to medications for Medicaid beneficiaries. See HHS Office of Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072 (Washington, D.C.: 2005).

claiming 340B discounts from drug manufacturers or qualifying for the program when they should not be, potentially increasing the likelihood that manufacturers will offset providing lower prices to covered entities with higher prices for others in the health care system. Additionally, manufacturers may be charging covered entities more than the 340B price for drugs, which would limit the benefit of the program for these entities.

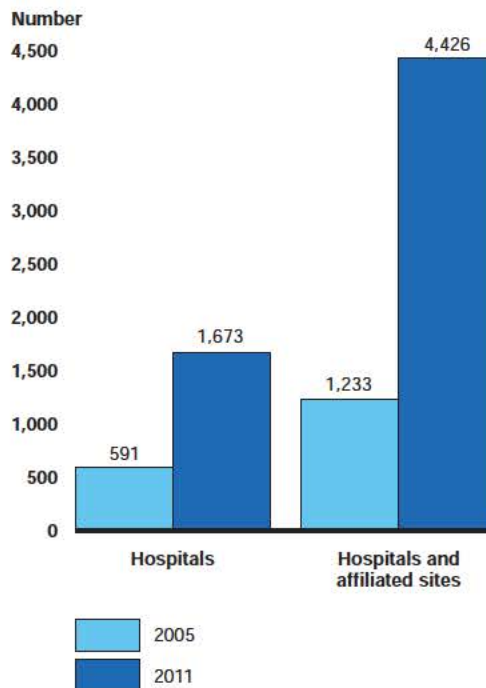
Changes in the Settings Where the 340B Program Is Used May Heighten Concerns about HRSA's Inadequate Oversight

Over time, the settings where the 340B program is used have shifted to more contract pharmacies and hospitals than in the past. According to HRSA officials, the number of covered entities using contract pharmacies has grown rapidly since its new multiple contract pharmacy guidance was issued in March 2010—as of July 2011, there were over 7,000 contract pharmacy arrangements in the program.⁶¹ Hospitals' participation in the 340B program has also grown markedly in recent years. In 2011, the number of hospitals participating in the program was nearly three times what it was in 2005, and the number of these organizations, including their affiliated sites, was close to four times what it was in 2005 (see fig. 2).⁶² Further, although participation in the 340B program has increased among other covered entity types over time, hospitals' participation in the 340B program has grown faster than that of federal grantees. In 2005, hospitals represented 10 percent of program participants, and as of July 2011, they represented 27 percent.

⁶¹HRSA was unable to provide the precise rate of growth of contract pharmacies within the 340B program due to data limitations. Specifically, HRSA currently only tracks contract pharmacy arrangements and is working to develop the ability to capture individual contract pharmacies. Data on the number of contract pharmacy arrangements are the most recent available from HRSA's covered entity database.

⁶²One reason for hospital growth could be that more hospitals may have become eligible as a result of state-level Medicaid expansions in recent years. The number of Medicaid patients served by a hospital affects its DSH adjustment percentage, which helps determine hospital eligibility for the 340B program.

Figure 2: 340B Program Participation among Hospitals and Their Affiliated Sites, 2005 and 2011



Source: GAO analysis of HRSA data.

Note: 2005 was the earliest year data were reliable for hospitals without their affiliated sites.

Increased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants' self-policing to oversee the program. Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies. For example, contract pharmacies are more likely to serve both patients of covered entities and others in the community; in these cases more sophisticated inventory tracking systems must be in place to ensure that 340B drugs are not diverted—intentionally or unintentionally—to non-340B patients.⁶³

⁶³ Some covered entities have in-house pharmacies that also serve as retail pharmacies for the broader community. However, among the covered entities we interviewed, we found that this was not often the case.

Also, for a number of reasons, operating the 340B program in the hospital environment creates more opportunities for drug diversion compared to other covered entity types. First, hospitals operate 340B pharmacies in settings where both inpatient and outpatient drugs are dispensed and must ensure that inpatients do not get 340B drugs. Second, hospitals tend to have more complex contracting arrangements and organizational structures than other entity types—340B drugs can be dispensed in multiple locations, including emergency rooms, on-site clinics, and off-site clinics. In light of this and given HRSA’s nonspecific guidance on the definition of a 340B patient, broad interpretations of the guidance may be more likely in the hospital setting and diversion harder to detect. Third, hospitals dispense a comparatively larger volume of drugs than other entity types—while representing 27 percent of participating covered entities, according to HRSA, DSH hospitals alone represent about 75 percent of all 340B drug purchases.

The increasing number of hospitals participating in the 340B program has raised other concerns for some stakeholders we interviewed, such as drug manufacturers, including whether all of these hospitals are in need of a discount drug program. Nearly a third of all hospitals in the U.S. currently participate in the 340B program, and HRSA estimates that more may be eligible.⁶⁴ The number of hospitals eligible to participate may increase due to PPACA’s Medicaid expansion, because the number of Medicaid patients served by a hospital affects its DSH adjustment percentage—one factor that determines hospital eligibility. Further, one organization we interviewed questioned whether the DSH adjustment percentage is the best measure to determine hospitals’ eligibility for the 340B program, because of research indicating that it may not be an adequate proxy for the amount of uncompensated care a hospital provides.⁶⁵ The DSH hospitals we interviewed reported a wide range of payer mixes—with the percentage of Medicaid and uninsured patients ranging from about 15 percent of total patient volume for one hospital to about 85 percent for another. However, payer mix may not be the only factor to consider when identifying hospitals that provide care to the

⁶⁴According to HRSA, over 400 additional DSH hospitals may be eligible for the 340B program based on their DSH adjustment percentage. This estimate does not include the additional hospital types made eligible for the program through PPACA.

⁶⁵See MedPAC, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: 2007), pp.78-79.

medically underserved and are part of the health care safety net. There is no established definition of a safety net hospital, and some researchers have argued that it should include factors other than payer mix, for example the disproportionate provision of critical services, that are either too expensive or unprofitable for other hospitals to provide, such as emergency room or trauma care.⁶⁶

HRSA's Plans to Improve Oversight of the 340B Program Are Uncertain and May Not Address All Areas of Concern

While PPACA's 340B program integrity provisions address many of the deficiencies in HRSA's current approach to oversight, the agency has taken few steps to implement these provisions. PPACA requires HRSA to increase oversight of both covered entities and manufacturers, and outlines specific steps for HRSA to take in accomplishing this goal. (See table 2 for the 340B program integrity provisions included in PPACA.) However, according to officials, the agency does not have adequate funding to implement the integrity provisions. Officials also noted that once funding is secured, it could take several years to develop the systems and regulatory structure necessary to implement them.

⁶⁶See for example, Barbara Wynn, et. al., "Analysis of the Joint Distribution of Disproportionate Share Hospital Payments," *PM-1387-ASPE* (Washington, D.C.: 2002); and Megan McHugh, Raymond Kang, and Romana Hasnain-Wynia, "Understanding the Safety Net: Inpatient Quality of Care Varies Based on How One Defines Safety-Net Hospitals," *Med Care Research and Review*, published online April 27, 2009.

Table 2: Key 340B Program Integrity Provisions Included in PPACA

Program participant	Requirements for HRSA	Required start date	Implementation status as of August 2011
Covered entities	Conduct annual recertification of eligibility for all covered entity types.	Not specified ^a	Developing implementation plan ^b
	Develop more detailed guidance on the procedures covered entities can follow to avoid the Medicaid duplicate discount.	Not specified ^a	Not started
	Establish a standard identification system for all covered entities by which each covered entity site can be identified for the purposes of ordering, purchasing, and delivery of 340B drugs.	Not specified ^a	Not started
	Impose certain sanctions on covered entities that knowingly and intentionally divert 340B drugs, by one or more of the following: <ul style="list-style-type: none"> requiring a covered entity to pay manufacturers interest on the discounts they received for those drugs; if the violation was also systematic and egregious, terminating the covered entity from the program and prohibiting re-enrollment for a period of time; and referral to federal authorities. 	Not specified ^a	Not started
Manufacturers	Improve mechanisms to ensure manufacturers charge the correct 340B prices on drugs, including: <ul style="list-style-type: none"> making a centralized list of HRSA-verified 340B prices available to covered entities, conducting selective audits of manufacturers, and establishing procedures by which manufacturers repay covered entities for overcharges. 	Not specified ^a	Not started
	Impose civil monetary penalties on manufacturers that knowingly and intentionally charge covered entities more than the 340B price.	Must issue regulations 180 days after enactment	Issued advanced notice of proposed rulemaking
Both	Develop a formal dispute resolution process, including: <ul style="list-style-type: none"> establishing procedures for covered entities to obtain information from manufacturers,^c and requiring manufacturers to audit covered entities prior to submitting a request to initiate the dispute resolution process. 	Must issue regulations 180 days after enactment	Issued advanced notice of proposed rulemaking

Source: GAO analysis of Pub. L. No. 111-148, § 7102, 124 Stat. 119, 823 and interviews with HRSA officials.

^aPPACA provides that these activities are to be conducted from amounts appropriated under a new authorization of appropriations. As of August 2011, no such appropriations have occurred.

^bHRSA officials told us that the Office of Pharmacy Affairs' fiscal year 2011 budget allowed for the planning of a phased approach to recertification of all entity types, which is scheduled to begin in the fall of 2011. As of August 2011, officials were not able to tell us which entity types would be phased in first.

^cPrior to PPACA, covered entities did not have access to 340B pricing data in order to monitor manufacturers because the Social Security Act prohibited the disclosure of the data by HRSA and state Medicaid agencies. 42 U.S.C. § 1396r-8(b)(3)(D). PPACA added a provision to Section 340B requiring that covered entities be allowed access to 340B pricing data. Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 824 (adding 42 U.S.C. § 256b(d)(1)(iii)).

Independent of the provisions in PPACA, HRSA also has recently developed guidance to further specify the definition of a 340B patient. While the Office of Management and Budget completed its review of this definition in April 2011, as of August 2011, HRSA had not yet released it for stakeholder comment. In 2007, HRSA also proposed updating this guidance, but it was never finalized.⁶⁷

Even if HRSA implements PPACA's provisions and updates its definition of a patient, these steps may not be sufficient to address all areas of concern. For example, PPACA specifically requires HRSA to conduct selective audits of manufacturers, but it did not establish the same requirement for audits of covered entities. As such, the effectiveness of HRSA's oversight of covered entities will, in part, be dependent on what additional steps the agency takes to ensure program integrity. Similarly, if in implementing PPACA's provision prohibiting manufacturers from discriminating against covered entities in the sale of 340B drugs, HRSA does not add specificity to the existing nondiscrimination guidance, it may be inadequate to ensure that all providers are able to equitably access drugs, particularly when manufacturers restrict the distribution of drugs at 340B prices. Also, as part of its 2007 proposed guidance on the definition of a patient, HRSA requested stakeholder comment on the elements that should be required in private, nonprofit hospitals' contracts with state or local governments as well as the different situations in which hospitals that are not publicly owned or operated should be formally granted government powers. However, HRSA officials told us that they have not issued additional guidance on these issues, and that they are not addressed in the clarifying guidance on the definition of a patient currently awaiting agency approval.

Conclusions

The 340B program allows certain providers within the U.S. health care safety net to stretch federal resources to reach more eligible patients and provide more comprehensive services, and we found that the covered entities we interviewed reported using it for these purposes. However, HRSA's current approach to oversight does not ensure 340B program integrity, and raises concerns that may be exacerbated by changes within the program. According to HRSA, the agency largely relies on

⁶⁷Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of a "Patient," 72 Fed. Reg. 1543 (Jan. 12, 2007).

participants' self-policing to ensure compliance with program requirements, and has never conducted an audit of covered entities or drug manufacturers. As a result, HRSA may not know when participants are engaging in practices that are not in compliance. Furthermore, we found that HRSA has not always provided covered entities and drug manufacturers with guidance that includes the necessary specificity on how to comply with program requirements. There also is evidence to suggest that participants may be interpreting guidance in ways that are inconsistent with the agency's intent. Finally, participants have little incentive to comply with program requirements, because few have faced sanctions for non-compliance. With the program's expansion, program integrity issues may take on even greater significance unless effective mechanisms to monitor and address program violations, as well as more specific guidance are put in place. For covered entities, this may be particularly true in settings where there is heightened concern about the opportunities for the diversion of 340B drugs.

PPACA outlined a number of provisions that, if implemented, will help improve many of the 340B program integrity issues we identified. For example, PPACA requires HRSA to recertify eligibility for all covered entity types on an annual basis, which would help ensure entities that lose eligibility for the program do not remain enrolled. Additionally, PPACA requires HRSA to develop a formal dispute resolution process, including procedures for covered entities to obtain information from manufacturers, and maintain a centralized list of 340B prices—provisions that would help ensure covered entities and manufacturers are better able to identify and resolve suspected violations. PPACA also requires HRSA to institute monetary penalties for covered entities and manufacturers, which gives program participants more incentive to comply with program requirements. Finally, PPACA requires HRSA to conduct more direct oversight of manufacturers, including conducting selective audits to ensure that they are charging covered entities the correct 340B price.

However, we identified other program integrity issues that HRSA should also address. For example, the law does not require HRSA to audit covered entities or further specify the agency's definition of a 340B patient. While HRSA has developed new proposed guidance on this definition, it is uncertain when, or if, the guidance will be finalized. Because the discounts on 340B drugs can be substantial, it is important for HRSA to ensure that covered entities only purchase them for eligible patients both by issuing more specific guidance and by conducting audits of covered entities to prevent diversion. Additionally, while PPACA included a provision prohibiting manufacturers from discriminating against

covered entities in the sale of 340B drugs, HRSA does not plan to make any changes to or further specify its related nondiscrimination guidance. Absent additional oversight by the agency, including more specific guidance, access challenges covered entities have faced when manufacturers' have restricted distribution of IVIG at 340B prices may continue and similar challenges could arise for other drugs in the future.

Also, current HRSA guidance may allow some entities to be eligible for the program that should not be. Hospitals qualify for the 340B program in part based on their DSH adjustment percentage. Even though the PHSA establishes additional eligibility requirements for hospitals that are not publicly owned or operated, these requirements are broad, and HRSA has not issued more specific guidance to implement them. We found that nearly a third of all hospitals in the U.S. are participating in the 340B program, more are currently eligible and not participating, and more may become eligible as Medicaid is expanded through PPACA. As the number of covered entities enrolled in the 340B program increases and more drugs are purchased at 340B prices, there is the potential for unintended consequences, such as cost-shifting to other parts of the health care system. As such, it is important that HRSA take additional action to ensure that eligibility for the 340B program is appropriately targeted. While HRSA officials reported that the agency does not have the resources to implement the PPACA provisions or otherwise increase oversight of the 340B program, limited resources could be prioritized to address areas of greatest risk to the program.

Recommendations for Executive Action

PPACA contained several important program integrity provisions for the 340B program, and additional steps can also ensure appropriate use of the program. Therefore, we recommend that the Secretary of HHS instruct the administrator of HRSA to take the following four actions to strengthen oversight:

- conduct selective audits of 340B covered entities to deter potential diversion;
- finalize new, more specific guidance on the definition of a 340B patient;
- further specify its 340B nondiscrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices; and

-
- issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B program.

Agency Comments and Our Evaluation

In commenting on a draft of this report, HHS stated that it agreed with our recommendations. HHS also had additional comments on several content areas of the report, and we made changes as appropriate to address these comments. (HHS' comments are reprinted in appendix III.) Finally, HHS provided technical comments, which we incorporated as appropriate.

HHS stated that HRSA would continue to work on 340B program integrity efforts and prioritize these efforts based on available funding. HHS also outlined steps that HRSA plans to take in response to each of our recommendations. While we appreciate HHS' commitment to improving oversight of the 340B program, we are concerned that the steps are not sufficient to ensure adequate oversight.

With regard to our first recommendation that HRSA conduct selective audits of covered entities to deter potential diversion, HHS stated that HRSA will continue working with manufacturers to identify and address potential diversion and implement a plan to better educate covered entities about diversion. However, HHS did not state that HRSA will conduct its own audits of covered entities and we reiterate the importance of the agency doing so as part of its ongoing oversight responsibilities.

With regard to our second recommendation that HRSA finalize new, more specific guidance on the definition of a 340B patient, HHS stated that HRSA will review the draft of proposed guidance to update the definition and revise this guidance in light of changes in PPACA. While we agree that it may be important for HRSA to consider the impact of PPACA on the definition, given that PPACA became law more than a year ago, and the potential for broad interpretations of current guidance, we encourage HRSA to complete its review in a timely fashion.

With regard to our third recommendation, that HRSA further specify its non-discrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices, HHS stated that HRSA will: implement a plan to specify existing policy regarding 340B non-discrimination and drug distribution; provide clearer guidance to manufacturers for working with HRSA and develop specific allocation

plans where needed; and continue to work with the Department of Justice when fair, voluntary allocation plans are not developed. However, we are concerned that these steps do not require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices. Without taking this step, HRSA may not know when manufacturers are inequitably distributing drugs to covered entities and non-340B providers.

With regard to our fourth recommendation that HRSA issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B program, HHS stated that HRSA will implement a plan to better educate covered entities on existing criteria for hospital participation in the program and initiate a phased approach to recertifying eligibility for all participating covered entities. Here, we are concerned that these steps do not include further specification of eligibility criteria for hospitals that are not publicly owned or operated, because we determined that additional specification of statutory requirements was needed to ensure that the 340B program is appropriately targeted.

We are sending copies of this report to the Secretary of HHS and appropriate congressional committees. In addition, the report is available at no charge on the GAO web site at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or at draperd@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.



Debra A. Draper
Director, Health Care

Appendix I: Selection of Interviews with Program Stakeholders

Type of stakeholder	Number of stakeholders interviewed	Interview details
Covered entities	29	<p>27 were selected to take into account certain criteria:</p> <ul style="list-style-type: none"> Entity Type: <ul style="list-style-type: none"> We selected five types of covered entities and specifically interviewed: 7 federally qualified health centers (FQHC), 5 disproportionate share hospital (DSH) hospitals, 5 hemophilia treatment centers, 5 family planning clinics, and 5 AIDS Drug Assistance Programs (ADAP). (See appendix II for a list of all entities eligible to participate in the program.) We picked these types based on: <ul style="list-style-type: none"> variation in operational structure, variation in services and drugs provided, high levels of 340B participation, experience with the program, and potential difficulty accessing drugs at 340B prices. Location: <ul style="list-style-type: none"> We selected entities in five states: Illinois, Massachusetts, Tennessee, Texas, and Utah. States were selected based on variation in a number of factors, including: geography, percent of uninsured individuals, and Medicaid reimbursement policies.^a We included Massachusetts to gain a better understanding of the potential effect of the Patient Protection and Affordable Care Act (PPACA) health insurance reforms on the 340B program.^b We used information provided by trade organizations representing covered entities to help select individual covered entities to interview. <p>2 additional DSH hospitals were selected based on concerns raised in stakeholder interviews about how these entities were using the program.</p>
Drug manufacturers	6	Selected based on market share and those that produce drugs with reported challenges related to their distribution at 340B prices.
Organizations representing drug manufacturers and others involved in drug distribution	6	Includes 4 manufacturer trade organizations, 1 distributor, and 1 pharmacy benefits manager. ^c

**Appendix I: Selection of Interviews with
Program Stakeholders**

Type of stakeholder	Number of stakeholders interviewed	Interview details
Organizations representing providers	16	Includes organizations representing providers, including covered entities and non-340B providers: <ul style="list-style-type: none"> • 9 organizations that represent covered entities, including 6 trade organizations and 3 private companies that provide services and information technology to help covered entities establish and manage their 340B programs. • 2 organizations representing non-340B providers, including 1 trade organization and 1 non-340B provider. • 5 organizations that represent both covered entities and non-340B providers, including 3 trade organizations and 2 group purchasing organizations (GPO).^d
Federal agencies and contractors	4	HRSA, the contractors that help administer the 340B program, and the Centers for Medicare & Medicaid Services.
Total	61	

Source: GAO.

^aMedicaid is a joint federal-state program that finances health care for certain categories of low-income individuals.

^bIn 2006, Massachusetts implemented comprehensive state-level health insurance reform that was similar to PPACA's national-level reform.

^cDistributors manage the sale of drugs to purchasers on behalf of manufacturers. Pharmacy benefit managers administer the prescription drug benefits of health insurance plans on behalf of plan sponsors.

^dGPOs contract with providers, such as hospitals, and, on behalf of their members, aggregate purchasing volume to negotiate discounts on drugs from drug manufacturers or distributors.

Appendix II: Select Information on Entities Eligible to Participate in the 340B Program

Entity type	How entity qualifies for 340B	Description of covered entity type	Year added to 340B program	Number of sites enrolled by entity type (July 1, 2011) ^a	Administering agency within the Department of Health Human Services (HHS)
Federal Grantees					
Federally-qualified health center (FQHC) ^{b,c}	Receives a section 330 grant under the Public Health Service Act (PHSA) (42 U.S.C. § 254b); meets the requirements to receive such a grant; or is an outpatient health program or facility operated by certain tribal or urban Indian organizations	Urban or rural health centers that provide comprehensive community-based primary and preventive care services to medically underserved populations.	1992 ^d	4,826	Health Resources and Services Administration (HRSA)
Urban Indian organizations ^e	Receives funds under title V of the Indian Health Care Improvement Act (25 U.S.C. §§1651 et seq.)	Provide a variety of health programs to eligible individuals.	1992 ^d	26	Indian Health Service
Family planning clinics (Title X)	Receives a grant or contract under Section 1001 PHSA (42 U.S.C. § 300)	Provide comprehensive family planning services.	1992 ^d	3,868	Office of Population Affairs
Sexually transmitted diseases grantee	Receives funds under Section 318 of the PHSA (42 U.S.C. § 247c) and is certified by the Secretary of HHS	Provide screening and treatment for sexually transmitted diseases.	1992 ^d	1,472	Centers for Disease Control and Prevention
Tuberculosis grantee	Receives funds under Section 317E of the PHSA (42 U.S.C. § 247b-6) and is certified by the Secretary of HHS	Provide treatment for tuberculosis.	1992 ^d	1,221	Centers for Disease Control and Prevention
Native Hawaiian Health Centers	Receives funds under the Native Hawaiian Health Care Act of 1988 (42 U.S.C. §§ 11701 et seq.)	Provide comprehensive health promotion and disease prevention services to Native Hawaiians.	1992 ^d	11	HRSA
State-operated Ryan White AIDS Drug Assistance Program (ADAP)	Receives financial assistance under title XXVI of the PHSA (42 U.S.C. §§ 300ff-11 et seq.)	Serve as a “payer of last resort” to cover the cost of providing HIV-related medications to low-income individuals who are uninsured or underinsured and cannot afford to pay for drugs or who cannot afford their health insurance coverage for drugs.	1992 ^d	90 ^f	HRSA

**Appendix II: Select Information on Entities
Eligible to Participate in the 340B Program**

Entity type	How entity qualifies for 340B	Description of covered entity type	Year added to 340B program	Number of sites enrolled by entity type (July 1, 2011) ^a	Administering agency within the Department of Health Human Services (HHS)
Other Ryan White grantees	Receives a grant under Part C of title XXVI of the PHSA or non-governmental grantees that receive any financial assistance under title XXVI of the PHSA if certified by the Secretary of HHS	Provide primary care and support services to individuals with HIV or AIDS.	1992 ^d	520	HRSA
Hemophilia treatment centers	Receives a grant under section 501(a)(2) of the Social Security Act (42 U.S.C § 701(a)(2))	Provide medical care to individuals with hemophilia.	1992 ^d	99	HRSA
Black lung clinics	Receives funds under Section 427(a) of the Black Lung Benefits Act (30 U.S.C. § 937(a))	Provide medical treatment to individuals disabled from pneumoconiosis (black lung) as a result of their employment at U.S. coal mines.	1992 ^d	13	HRSA
Hospitals					
Disproportionate share hospitals (DSH)	DSH as defined under Section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. § 1395ww(d)(1)(B)) with a DSH adjustment percentage greater than 11.75 ^g	General acute care hospitals paid under the Medicare inpatient prospective payment system.	1992 ^d	3,061	Centers for Medicare & Medicaid Services (CMS)
Children's hospitals	Children's hospital as described under Section 1886 (d)(1)(B)(iii) of the Social Security Act with a DSH adjustment percentage greater than 11.75 ^g	Primarily provide services to individuals under 18 years of age.	2006 ^h	147	CMS
Critical access hospitals	Critical access hospital as determined under Section 1820(c)(2) of the Social Security Act (42 U.S.C. § 1395i-4(c)(2)) (no DSH requirement) ^g	Located in rural areas, provide 24-hour emergency care services, and have no more than 25 inpatient beds.	2010 ⁱ	941	CMS and HRSA
Sole Community Hospitals	Sole community hospital as defined under Section 1886(d)(5)(D)(iii) of the Social Security Act (42 U.S.C. § 1395ww(d)(5)(D)(iii)) with a DSH adjustment percentage equal to or greater than 8 ^g	Isolated from other hospitals by distance, weather, or travel conditions.	2010 ⁱ	200	CMS and HRSA

**Appendix II: Select Information on Entities
Eligible to Participate in the 340B Program**

Entity type	How entity qualifies for 340B	Description of covered entity type	Year added to 340B program	Number of sites enrolled by entity type (July 1, 2011) ^a	Administering agency within the Department of Health Human Services (HHS)
Rural Referral Centers	Rural referral center as defined under Section 1886(d)(5)(C)(i) of the Social Security Act (42 U.S.C. §1395ww(d)(5)(C)(i)) with a DSH adjustment percentage equal to or greater than 8 ^g	Large rural hospitals that provide services for patients from a wide geographic area.	2010 ^f	72	CMS and HRSA
Free-standing cancer hospitals	Free-standing cancer hospital as described under Section 1886(d)(1)(B)(v) of the Social Security Act (42 U.S.C. § 1395ww(d)(1)(B)(v)) with a DSH adjustment percentage greater than 11.75 ^g	Not a unit of another hospital, has a primary purpose of treating or conducting research on cancer.	2010 ^f	5	CMS
Total				16,572	

Source: GAO analysis of federal laws and regulations.

^aData are the most recent available from HRSA's covered entity database and represent both covered entities and their associated sites. Because a covered entity may enroll under any and all eligible grant types it receives, it is possible that a site is reflected in the database more than once. However, HRSA estimates that this overlap represents less than 5 percent of all listings in the database.

^bNot all FQHCs receive federal grants. Providers that meet all of the requirements for the FQHC program but do not receive federal grants are referred to as FQHC look-alikes and are eligible to participate in the 340B program.

^cThis category includes: FQHC look-alikes; Consolidated Health Centers; Migrant Health Centers; Health Care for the Homeless; Healthy Schools/Healthy Communities; Health Centers for Residents of Public Housing; and Tribal Organizations created under the Indian Self Determination Act (Pub. L. No. 93-638) and administered by the Indian Health Service.

^dEligible to participate in the 340B program from its inception. See Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967.

^eSection 1905(l)(2)(B) of the Social Security Act includes outpatient health programs or facilities operated by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act for the provision of primary health services in the definition of FQHCs.

^fAccording to HRSA, some states have both direct purchase and rebate programs, which are counted separately in the 340B covered entity database, which is the reason for the difference in the number of ADAPs in the database versus the number of states that have ADAP programs overall.

^gFacility must also be (1) owned or operated by a state or local government, (2) a public or private, nonprofit corporation that is formally delegated governmental powers by a unit of state or local government, or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low income individuals who are not eligible for Medicaid or Medicare. Medicaid is the joint federal-state program that finances health care for certain low-income people, and Medicare is the federal health care program for the elderly and disabled. Children's hospitals and free-standing cancer hospitals do not receive payments under Medicare's inpatient prospective payment system; however, they must have a payer mix that would result in a DSH adjustment percentage greater than 11.75 percent. Facilities except critical access hospitals, Rural Referral Centers, and Sole Community Hospitals, must not obtain covered outpatient drugs through group purchasing.

**Appendix II: Select Information on Entities
Eligible to Participate in the 340B Program**

^hWhile PPACA explicitly added children's hospitals to the list of covered entities under the 340B program in the PHSA, they were originally made eligible under the Social Security Act through the Deficit Reduction Act of 2005. Pub. L. No. 109-171, § 6004, 120 Stat. 4, 61 (2006).

ⁱBecame eligible to participate in the 340B program under PPACA. Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302, 124 Stat. 1029, 1082.

Appendix III: Comments from the Department of Health and Human Services

Note: Page numbers in the draft report may differ from those in this report.



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

Debra A. Draper
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

SEP 07 2011

Dear Ms. Draper:

Attached are comments on the U.S. Government Accountability Office's (GAO) draft report entitled: "DRUG PRICING: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement" (GAO-11-836).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

A handwritten signature in cursive script, reading "Jim R. Esquea", is positioned above the typed name.

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

The Department appreciates the opportunity to review and comment on this draft report. We offer the following general comments on several content areas of the report:

The extent to which covered entities generate 340B revenue, factors that affect their revenue generation, and how entities use the program:

On Page 16, the report states that in Massachusetts where the state implemented universal health care, low-income patients gained private insurance, but "these patients often could not afford associated copayment or deductibles and the entity covered these costs". HRSA requests that the report reflect that this finding is consistent with the Health Resources and Services Administration's (HRSA) assessment that low-income patients will continue to require such assistance and the covered entities will provide valuable services to the safety net community.

On Page 18, the report states that "Even though the uses of revenue generated through the 340B Program were for similar purposes, some covered entities relied on 340B revenue more than others." The report goes on to state differences in revenue for FQHCs versus hemophilia centers. HRSA requests that the following explanation be incorporated into the report: Because each 340B entity type is unique in the types of services it provides and the patients it treats, the drug purchases of each entity type vary greatly (*i.e.*, generics versus brand or certain specialty drugs); therefore, their savings will also vary greatly.

Regarding how manufacturers' distribution of drugs at 340B prices affects providers' access to drugs, whether those providers are covered entities or non-340B providers:

On Page 20, the report states that "One IVIG manufacturer reported that it restricted its distribution of IVIG by allocating its supply based on the amount of drug purchased by providers in 2004--allocating 95 percent of the projected monthly sales to non-340B providers and the remaining 5 percent to covered entities at the 340B Price" and "this manufacturer states that its distribution was fair and changing the distribution plans to increase the amount of IVIG drugs available at 340B prices could negatively affect non-340B providers' access to the drugs." HRSA requests that the report be edited to include:

"HRSA does not believe that using the 2004 allocation of 95 percent to non-340B providers and 5 percent to 340B providers for a critical life saving drug is fair or sufficient. In 2005, there were 77 Hemophilia Treatment Centers and 591 Disproportionate Share Hospitals (DSH) purchasing IVIG through the 340B Program. This number has increased significantly to 99 Hemophilia Treatment Centers and

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

1,673 hospitals that now include children's hospitals, critical access hospitals, disproportionate share hospitals, free standing cancer hospitals, and rural referral centers. The allocation of IVIG drugs to 340B providers needs to be correlated to the increase in the 340B hospitals, as many of the same hospitals that purchased IVIG with no problems as non-340B providers in 2004 are now having tremendous difficulty in purchasing IVIG in 2011 as 340B providers. With 340B hospitals representing almost 33 percent of the hospitals of in the U.S. in 2011, 5 percent allocation for a life saving drug is not adequate."

On Page 21, the report states that some covered entities have stockpiled drugs when the price of a drug dropped. HRSA recommends that the report note that HRSA has worked with manufacturers in the past during an expected drop in price to develop an allocation process that is equitable across 340B and non-340B entities to prevent stockpiling. In addition, HRSA also encourages manufacturers to work with the agency to develop allocation processes to prevent issues with stockpiling.

HRSA's oversight of the 340B Program

On Page 24, the report states that HRSA has not issued guidance specifying the criteria under which hospitals that are not publicly owned or operated can qualify for the 340B program. HRSA requests that the report reflect that while HRSA has not published formal guidance in this area, HRSA has both criteria and a process in place to ensure hospitals satisfy 340B requirements. These criteria are utilized during the enrollment process and include:

- The criteria for hospital eligibility to participate in the 340B Program is outlined in section 340B(a)(4)(L)(i) which states the hospital "is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this title." This information is on the HRSA Office of Pharmacy Affairs (OPA) website.
- Prior to enrolling a hospital into the Program, OPA verifies that the hospital meets the three statutory requirements for participation in the 340B program: 1) non-profit status is verified by IRS documentation; 2) DSH eligibility, if applicable, is verified by the Medicare-cost report and 3) private hospitals must have a contract with state or local governments to provide health care services to low income

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

individuals who are not entitled to benefits under Title XVIII of the Social Security Act or eligible for assistance under the State plan of Title XIX of the Social Security Act. As part of the registration process, the hospital must submit a form that attests to the aforementioned statement that is signed by both an authorized public official and a hospital executive. Contracts are selectively reviewed if further clarification is necessary.

- OPA provides hospitals a list of recommendations during the enrollment process that can be used in developing a contract. HRSA strongly recommends and encourages the covered entity to seek legal counsel when preparing these contracts.

On page 24, the report states that some stakeholders expressed concern about the application of the requirements against non-discrimination. The conclusion of the report states that absent additional guidance, "access challenges covered entities have faced when manufacturers' have restricted distribution of certain drugs at 340B prices may continue." The language in the conclusion suggests that several challenges are known and identified; however, in its report the only access challenges identified involved IVIG. HRSA has been working with the Department of Justice (DOJ) to evaluate and improve access to IVIG for 340B entities. HRSA recommends that GAO provide additional detail regarding the access challenges found in order for HRSA to address these concerns and take appropriate action.

On Page 25, the report states that HRSA verifies eligibility for 340B at enrollment, but does not periodically recertify eligibility for all covered entity types. HRSA requests that the report reflect that HRSA has been meeting the statutory requirement; HRSA recertified and continues to recertify STD, TB, and HIV/AIDS programs annually as expressly required under section 340B (a)(7) of the Public Health Services Act (42 U.S.C. 256b). These were the only entities that required annual certification by the Secretary prior to the PPACA. In addition, HRSA monitors DSH percentages and FQHC grant status on a quarterly basis. Each quarter OPA verifies the proprietary status of participating hospitals by matching its list of participating hospitals with CMS's list of hospitals to ensure that ineligible private hospitals are not participating. As a result of the PPACA, HRSA is required to annually recertify all 340B covered entities. OPA's FY2011 budget of \$4.4M will allow for the planning of and initiation of a phased approach to recertification to begin in fall of 2011.

On Page 31, footnote (a) states that no appropriation has occurred for annual recertification. HRSA recommends that this statement be replaced with the following, "HRSA program FY2011 budget of \$4.4M will allow for the planning and initiation of a phased approach to recertification to begin in fall 2011."

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

On Page 32, the report states that the PPACA specifically requires HRSA to conduct selective audits of manufacturers but it did not establish the same requirement for audits of covered entities. HRSA requests that the report clarify that the agency has had the authority to audit covered entities under section 340B(a)(5)(C) of the Public Health Service Act since the inception of the program.

GAO Recommendations

HRSA agrees with the recommendations and will continue to build on program integrity efforts and work to prioritize efforts based on funding. Implementation of a cost recovery fee as outlined in the FY 2012 President's budget would allow for the initiation of the implementation of all recommendations and program integrity provisions outlined in PPACA. The 340B Drug Pricing program integrity risk assessment is scheduled to begin in the fall of 2011.

GAO Recommendation #1: *Conduct selective audits of 340B covered entities to deter potential diversion.*

HRSA Actions:

- HRSA and the manufacturers have the authority to audit 340B covered entities. HRSA will continue to work with the manufacturers to identify potential diversion and work with manufacturers to develop audit plans where evidence suggests potential diversion may be occurring.
- HRSA will develop and implement a comprehensive educational and communication plan which will build on existing tools and resources, such as targeted webinars on diversion, peer to peer learning, FAQs, policy letters to covered entities, and more assistance to covered entities in assessing risk.

GAO Recommendation #2: *Finalize new, more specific guidance on the definition of a 340B patient.*

HRSA Actions:

- HRSA will review the draft of the proposed patient definition guidelines in view of PPACA changes and develop revised guidelines for publication.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

Recommendation #3: *Further specify its 340B non-discrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices.*

HRSA Actions:

- HRSA will develop and implement a comprehensive educational and communication plan which will specify the existing policy regarding 340B non-discrimination and drug distribution to include, webinars, and policy letters to manufacturers regarding non-discrimination guidance.
- HRSA will continue to work with manufacturers to provide clearer guidance for manufacturers on working with HRSA and develop specific allocation plans where needed.
- HRSA will continue to work with DOJ when fair, voluntary allocation plans are not developed.

Recommendation #4: Issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B Program.

HRSA Actions:

- HRSA will further publicize its existing criteria for hospital participation in the 340B program by placing the criteria and process on the program website and issuing policy letters to affected covered entities outlining these criteria.
- HRSA will initiate a phased approach to recertification for all participating entities, including hospitals, beginning in fall of 2011. This recertification process will enable HRSA to verify that hospitals continue to meet the statutory requirements for program participation.
- HRSA will develop and implement a comprehensive educational and communication plan which will build on existing tools and resources such as targeted webinars on the hospital criteria, peer to peer learning, FAQs, and letters to covered entities.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Debra A. Draper, (202) 512-7114 or draperd@gao.gov

Staff Acknowledgments

In addition to the contact named above, Gerardine Brennan, Assistant Director; Jennie Apter; Kristin Ekelund; Kelli Jones; Dawn Nelson; Rachel Svoboda; and Jennifer Whitworth made key contributions to this report.

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